Objections to the drawings have been addressed by the proposed amendments. Applicant points out that item numbers 28, 46, and 56 mentioned in the Office Action are already present in the drawings in figures 5 and/or 6.

The Office Action objects to the specification due to the mismatch between the item numbers in the specification and the item numbers in Figure 4. The proposed amendment to Figure 4 should address the objections to the specification.

The Office Action rejects claims 1 through 5 as anticipated by Swartz et al., Process and Device for the Treatment of Atrial Arrhythmia, U.S. Patent 5,938,660 (Aug. 17, 1999) under the assertion that Swartz discloses a device having a catheter body, a first balloon, a heating element, a suction lumen having a suction port, and different sources of energy used for catheter ablation such as direct current and RF energy. The Office Action then refers to Figures 2 through 7 of Swartz. With regard to claims 4 and 5, that it is inherent that the electrode is connected through wires to the RF energy source.

The rejection ignores limitations of the claims. Swartz does not disclose or hint at suction being applied to draw tissue of a vessel near a valve toward the heating element (a limitation present in all 5 claims). Instead, Swartz introduces a conductive media into the space between his two balloons and then applies RF energy to the conductive media to ablate a heart blood vessel. Thus, Swartz does not anticipate claims 1 through 5.

The Office Action characterizes item 28 in Swartz as a suction port, but Swartz describes item 28 as a conductive media opening. Swartz does not disclose a suction lumen as claimed by Applicant. The conductive media opening introduces the media used to conduct RF energy to the blood vessel in the heart. In one embodiment, Swartz proposed introduction of chemical ablating agent. For this embodiment, he provides a second opening to

permit the chemical ablating agent to be flushed from the pulmonary vein. He certainly does not suggest applying suction to pulmonary veins. Indeed, the Swartz device will not repair valves since Swartz does not attempt shrink the lumen he seeks to ablate, and provides no mechanism or feature for doing so.

Furthermore, Swartz would damage any valve or sphincter disposed between the two balloons, a consequence that frequently is not medically indicated. Swartz fills the area between the two balloons with RF energy, which is conducted by the conductive media to the entire inner surface of the blood vessel between the balloons. Thus, if the Swartz device were used to repair valves or sphincters then the valve or sphincter would be damaged along with the rest of the vessel tissue. Since damaging the valve or sphincter is frequently not medically indicated, the Swartz device would likely be detrimental to the patient. Thus, the limitations of claims 1 through 5 also cannot be inherent to Swartz.

The Office Action rejects claims 4 and 5 as obvious over Swartz in view of Laufer et al., Method of Treating a Bronchial Tube with a Bronchial Stenter Having Diametrically Adjustable Electrodes, U.S. Patent 6,283,989 (Sep. 24, 2001) under the assertion that Swartz inherently discloses wires.

The proposed combination does not result in the claimed inventions. Neither Swartz nor Laufer discloses a suction lumen. Accordingly, claims 4 and 5 are not obvious in view of Swartz and Laufer. Also, neither Swartz nor Laufer disclose a resistive heating element, and the Office Action makes no suggestion they do. While Swartz explicitly teaches against use of direct current, and Laufer does not mention direct current, neither reference mentions or suggests a resistive heating element.

Applicant has added new claims 9 and 10 directed to a valve or sphincter repair catheter. Neither Swartz nor the combination of Swartz and Laufer discloses or hints at the limitations of

claims 9 and 10, namely the placement of a pair or pairs of heating elements between the balloons. This structure allows application of heat to at least two distinct areas of body lumen located between the balloons when in place. There appears to be no reason for adopting such features in the cited references.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: July 15, 2002

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Reg. No. 48,504

Docket No. 212/262

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:	
Mollenauer	Art Unit: 3763
Serial No.: 09/598,852	
Filed: June 20, 2000	
For: Devices and Methods for Repair of Valves in the Human Body	Examiner: Thanh, L.

ATTACHMENT OF CLAIMS AND AMENDED SPECIFICATION PARAGRAPHS

The claims, including those amended by the Response submitted herewith on July 15, 2002, are as follows:

1. (unchanged) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body;

a heating element mounted on the distal end of the catheter, proximal to the first balloon;

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and a suction port located on the distal end of the catheter communicating from suction lumen to the exterior of the catheter body, said suction port being located proximal the heating element; whereby suction applied to the vessel through the suction port will draw the tissue of the vessel near the valve toward the heating element.

2. (unchanged) The device of claim 1 further comprising:

a second balloon located at the distal end of the catheter, proximal to the first balloon, the heating element and suction port, said second balloon being inflatable to a diameter greater than the catheter body distal end.

3. (unchanged) The device of claim 2 further comprising:

a second inflation lumen communicating from the proximal end of the catheter body to the second balloon on the distal end of the catheter body.

4. (unchanged) The device of claim 1 further comprising:

a pair of wires running from the heating element to the proximal end of the catheter, said wires adapted to electrically connect the heating element to direct current power supply; and

wherein the heating element is a resistive heating element.

5. (unchanged) The device of claim 1 further comprising:

a wire running from the heating element to the proximal end of the catheter, said wire adapted to electrically connect the heating element to a radiofrequency power supply; and

wherein the heating element is a radiofrequency electrode adapted for transmission of radiofrequency energy into the tissue of the vessel.

9. (new) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

a first heating element mounted on the distal end of the catheter, proximal to the first balloon;

a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon and proximal to the first heating element, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second inflation lumen is in fluid communication with the second balloon;

a second heating element mounted on the distal end of the catheter, distal to the second balloon and proximal to the first heating element;

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and at least one suction port located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, said at least one suction port being located proximal to the first heating element and distal to the second heating element; whereby suction applied to the vessel through the at least one suction port will draw the tissue of the vessel near the valve toward the first and second heating elements.

10. (new) A device for treating a plurality of incompetent anatomical valves or sphincters within the body of a patient, wherein said plurality of valves or sphincters control flow of fluid through a vessel of the body and are supported by tissue of the vessel near the plurality of valves, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second inflation lumen is in fluid communication with the second balloon;

a plurality of heating elements mounted on the distal end of the catheter body, wherein each of the plurality of heating elements are disposed in series along the length of the catheter body, wherein two succeeding heating elements comprise a pair of heating elements, and wherein the pair of heating elements are further disposed on the catheter body such that a section of catheter body separates each pair of heating elements; and

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body; and

a plurality of suction ports located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, wherein at least one of the plurality of suction ports is disposed between each pair of heating elements, whereby suction applied to the vessel through the plurality of suction ports will draw the tissue of the vessel near each of the plurality of valves toward each pair of heating elements.

End